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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,327	09/10/2004	Mark C. Peterman	AL001	5326

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EXAMINER	
DAM, DUSTIN Q	

ART UNIT	PAPER NUMBER
1795	

NOTIFICATION DATE	DELIVERY MODE
09/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ulman@nupat.com

Office Action Summary	Application No.	Applicant(s)	
	10/711,327	PETERMAN ET AL.	
	Examiner	Art Unit	
	DUSTIN Q. DAM	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *6-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 & 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 6, 2009 has been entered.

2. The rejections of claims 1-5 and 9 under 35 U.S.C. 103(a) previously presented in the Office Action sent April 29, 2009 have been maintained and presented below.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over JESPERSEN et al. (U.S. PG-Pub 2006/0121464 A1) in view of CHERUKURI et al. (U.S. Patent 5,603,351).

a. With regards to claim 1, JESPERSEN et al. discloses a device comprising a microfluidic channel (5, FIG. 3 & see **[0050-0059]**) with openings at each end (such as depicted in FIG. 3) and two or more apertures in the channel walls (7, FIG. 3 & see **[0057]**; although FIG. 3 appears to depict a single aperture, it is interpreted that a plurality of apertures exist on membrane 3 in light of Example 2 which discloses using the device of FIG. 3, **[0067]**, which comprises multiple "sites" which are interpreted to read on the apertures, see **[0070-0071]**), micropumps placed in or near the openings at either end of the channel (9, FIG. 3) wherein the apertures are in contact with an external fluid bath (4, FIG. 3) while the openings are isolated from the bath (as depicted in FIG. 3).

JESPERSEN et al. does not appear to explicitly disclose a device wherein the micropumps are specifically electrically driven which comprise electrodes and a power supply. The only difference between the invention, as claimed in claim 1 of the instant application, and the device of JESPERSEN et al. is the explicit disclosure of the claimed driving force to move the reagent fluid through the system.

However, CHERUKURI et al. discloses driving fluid through a microfluidic device via “micropumps” and specifically discloses the micropumps operate via an electrical power source which provides voltage to electrodes (last paragraph of column 2 joining beginning of column 3, "electrical contacts" and "voltage source"). As made

evident by CHERUKURI et al., micropumps are conventionally designed with electrodes and power sources to electrokinetically drive fluid through microfluidic devices.

Thus, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the device of JESPERSEN et al., to include the micropump design of CHERUKURI et al. because a simple substitution of known elements which are known in the art to perform the same function, in the instant case driving fluid, is a matter of obviousness as one would expect the predictable results of electrokinetic fluid movement in the combination (See MPEP 2141{III}{B}). Although given the disclosure of JESPERSEN et al. in FIG. 3 and example 2 which appears to disclose a plurality of apertures, in the alternative, it would have been obvious to duplicate the aperture 7, FIG. 3 of JESPERSEN et al. as the duplication of an element is a matter of obviousness (See MPEP 2144.04{VI}{B}).

b. With regards to claim 2, independent claim 1 is obvious over JESPERSEN et al. in view of CHERUKURI et al. under 35 U.S.C. 103(a) as discussed above. The combination of JESPERSEN et al. and CHERUKURI et al. discloses a device comprising electrokinetic pumps applying a voltage on each end of the microchannel (JESPERSEN et al.: FIG. 3) via a power source. The power source is structurally capable of providing several distinct current paths from one end of the channel to the other with and structurally capable of providing current to flow along all of these paths (such as each of the plurality of apertures providing distinct current paths especially when cells block the apertures; also see JESPERSEN et al.: **[0071]** which discloses detecting current around cell blocked apertures).

c. With regards to claim 3, independent claim 1 is obvious over JESPERSEN et al. in view of CHERUKURI et al. under 35 U.S.C. 103(a) as discussed above. The combination of JESPERSEN et al. and CHERUKURI et al. discloses a device comprising electrokinetic pumps applying a voltage on each end of the microchannel (JESPERSEN et al.: FIG. 3) via a power source. The power source is structurally capable of providing simultaneous flow of fluids through two or more apertures and a chemical concentration gradient is formed near the apertures (JESPERSEN et al.: as the buffer fluid 5, FIG. 3 flows via micropumps and cells begin to seal the apertures, some degree of simultaneous fluid flows through two or more apertures; a chemical concentration gradient is also formed such as when a cell blocks/seals an apertures, one side of the aperture will have a concentration of cells while the channel-side of the aperture will have no cell concentration).

d. With regards to claim 4, independent claim 1 is obvious over JESPERSEN et al. in view of CHERUKURI et al. under 35 U.S.C. 103(a) as discussed above. The combination of JESPERSEN et al. and CHERUKURI et al. discloses a device comprising a microchannel and apertures in the channel walls (see JESPERSEN et al.: FIG. 3).

The combination of JESPERSEN et al. in view of CHERUKURI et al. does not appear to explicitly disclose the claimed ranges of channel length, width, and aperture size.

However, the combination of JESPERSEN et al. in view of CHERUKURI et al. discloses aperture sizes in order to capture or seal the apertures with cells, similar to the instant invention (JESPERSEN et al.: **[0057]**).

Thus, at the time of the invention, it would have been a matter of obviousness to optimize the relative sizes of channel length, width, and aperture size and arrive at the claimed ranges through routine experimentation absent contrary support for unexpected results or range criticality (See MPEP 2144.05).

e. With regards to claim 5, independent claim 1 is obvious over JESPERSEN et al. in view of CHERUKURI et al. under 35 U.S.C. 103(a) as discussed above. The combination of JESPERSEN et al. and CHERUKURI et al. discloses a device comprising a microchannel and apertures in the channel walls with indentations in the channel near the apertures, such indentations being approximately the size of a living cell (such as sloped walls depicted in FIG. 2 & see **[0049]**).

f. With regards to claim 9, JESPERSEN et al. discloses a microfluidic device comprising a microfluidic channel defining a flow path for a fluid having a known concentration of a selected chemical (5, FIG. 3 & see **[0050-0059]**), the microfluidic channel comprising a plurality of apertures defined in the channel (7, FIG. 3 & see **[0057]**; although FIG. 3 appears to depict a single aperture, it is interpreted that a plurality of apertures exist on membrane 3 in light of Example 2 which discloses using the device of FIG. 3, **[0067]**, which comprises multiple "sites" which are interpreted to read on the apertures, see **[0070-0071]**) structurally capable of providing fluid communication between the channel and a reservoir (4, FIG. 3) containing a sample solution (such as depicted in FIG. 3 when aperture is unblocked/unsealed by a cell), and an inlet and an outlet that are isolated from the reservoir (each end of channel 5, FIG. 3), micropumps for inducing flow along the flow path (9, FIG. 3) and means for applying

pressure to the fluid (gravitational pressure as the inlet and outlet of channel 5 are open, FIG. 3) structurally capable of providing fluid flow simultaneously out of the channel at the apertures and forms a concentration gradient at the apertures along the channel such that cells cultured near each aperture are exposed to a separate concentration of the chemical corresponding to the location of the aperture along the concentration gradient. Regarding claims which contain various process or intended use limitations which do not further delineate the structure of the claimed invention from the structure of the prior art are given no patentable weight as the claims are filed in the statutory class of an apparatus.

JESPERSEN et al. does not appear to explicitly disclose a device wherein the micropumps are specifically electrically driven which comprise electrodes and a power supply. The only difference between the invention, as claimed in claim 1 of the instant application, and the device of JESPERSEN et al. is the explicit disclosure of the claimed driving force to move the reagent fluid through the system.

However, CHERUKURI et al. discloses driving fluid through a microfluidic device via “micropumps” and specifically discloses the micropumps operate via an electrical power source which provides voltage to electrodes (last paragraph of column 2 joining beginning of column 3, "electrical contacts" and "voltage source"). As made evident by CHERUKURI et al., micropumps are conventionally designed with electrodes and power sources to electrokinetically drive fluid through microfluidic devices.

Thus, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the device of JESPERSEN et al., to include the

micropump design of CHERUKURI et al. because a simple substitution of known elements which are known in the art to perform the same function, in the instant case driving fluid, is a matter of obviousness as one would expect the predictable results of electrokinetic fluid movement in the combination (See MPEP 2141{III}{B}). Although given the disclosure of JESPERSEN et al. in FIG. 3 and example 2 which appears to disclose a plurality of apertures, in the alternative, it would have been obvious to duplicate the aperture 7, FIG. 3 of JESPERSEN et al. as the duplication of an element is a matter of obviousness (See MPEP 2144.04{VI}{B}).

Response to Arguments

6. Applicant's arguments filed August 6, 2009 have been fully considered but they are not persuasive.

a. Applicant argues in the response filed August 6, 2009 that the rejections of claims 1-5 and 9 under 35 U.S.C. 103(a) are improper because not all of the claimed elements are disclosed in the references, specifically a plurality of apertures are not disclosed in the cited JESPERSON et al. reference. Applicant argues that the examiner's interpretation of the JESPERSON et al. reference is incorrect and asserts the JESPERSON et al. reference discloses "a suitable chip for patch clamp experiments is described in WO 02/9402". Applicant then relies on this statement to somehow conclude that certain portions disclosed in the WO 02/9402 are exclusively limiting the invention disclosed in FIG. 3 of the JESPERSON et al. (2006/0121464 A1) reference. Even if the chip in the WO 02/9402 reference is "suitable" for patch clamp experiments, being "suitable" in no way

exclusively limits the chip to only patch clamp methods. The examiner also does not concede that patch clamp methods cannot be preformed with a device including multiple apertures, however it is also noted that the invention, as elected, is filed in the statutory class of an apparatus. Furthermore, applicant's cited statement asserting that the device in FIG. 3 of the JESPERSON et al. (2006/0121464 A1) reference is "suitable" for patch clamp experiments is directly followed by a disclosure stating "For use in this invention the chip is ***modified*** to enable the extraction of mRNA from the cell and is as shown in FIG. 3." (See para. **[0067]**, JESPERSON et al. 2006/0121464 A1; emphasis added). The entirety of the JESPERSON et al. (2006/0121464 A1) reference's disclosure explaining example 2 (cited in Office Action) talks about a ***plurality*** of sites/apertures. Applicant then argues that the JESPERSON et al. (2006/0121464 A1) reference discloses "an ion channel-containing structure" and the use of a singular noun limits the device to only comprise one aperture. This assertion is a misrepresentation/mischaracterization of the JESPERSON et al. (2006/0121464 A1) reference which was taken out of context. The phrase "an ion channel-containing structure" does indeed appear in the JESPERSON et al. (2006/0121464 A1) reference but applicant's interpretation of that particular phrase is incorrect because the phrase is apart of a sentence that reads "The chip contains a planar substrate comprising a first surface part and an opposite second surface part, the first surface part having a ***plurality of sites each*** of which is adapted to hold an ion channel-containing structure." (See JESPERSON et al. (2006/0121464 A1) **[0068]** emphasis added). The interpretation of the JESPERSON et al. (2006/0121464 A1) reference is maintained and presented above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DUSTIN Q. DAM whose telephone number is (571)270-5120. The examiner can normally be reached on Monday through Thursday, 7:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571)272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

dd
August 28, 2009